Y-90 MICROSPHERE GUIDE

INFORMATION REQUIRED FOR LICENSING SIRTEX MEDICAL SIR-SPHERE Y-90 BRACHYTHERAPY DEVICES

NOTE: This document assumes that you have a Specific medical license and you wish to amend your license to permit use of a Sirtex Medical SIR-Sphere (Y-90) Microsphere brachytherapy devices. Accordingly, it is not necessary to submit information about calibration of survey instruments, radiation safety committee, personnel monitoring program, leak testing and ALARA program, unless any of these prior commitments change because of this amendment request. Address the following items in your amendment request.

I. Description of the Source(s) and Device(s)

A. Source description

NRC Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Sources NO. MA-1059-D-356-S

1. Radionuclide; Yttrium-90 (Y-90)
2. Manufacturer's name and model number: Sirtex Medical Limited SIR-Sphere
3. Maximum activity : SIR-Sphere 108 mCi/vial
4. Maximum Possession Limit: SPECIFIED BY LICENSEE

B. Device description

SIR-Sphere` NRC Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Sources NO. MA-1059-D-356-S

1. Manufacturer/Distributor: Sirtex Medical Limited/AEA Technology QSA, Inc.
2. Model name/number: SIR-Sphere
3. Device type: SIR-Sphere Brachytherapy Afterloader

II. Intended Use:

To be used for Intravascular Brachytherapy (IVB) treatments of hepatic carcinoma.

III. Proposed Users

A. Group 6 authorized users (radiation oncologists) or nuclear medicine physicians **(specify by name)** currently listed on the license who have had the manufacturer's training.

B. Commitment that the Group 6 authorized user (radiation oncologist) or nuclear medicine physicians currently listed on the license will provide direct supervision (physically present) and have authority for radiation safety.

C. Commit that the group 6 authorized user (radiation oncologist) or nuclear medicine physicians currently listed on the license will be the only individual operating the device during patient treatment.

IV. Training for Individuals

A. Confirm that initial training shall be provided by the manufacturer **or an authorized user who has been trained by the manufacturer.**

B. Outline topics covered in retraining and state the frequency of such retraining.

C. Commit to documenting all training records for inspection purposes.

V. Facilities

A. Specify where source shipments will be stored and who will transport sources to treatment room and back to storage areas.

B. Describe area security for each treatment room

C. For restricted areas:

1. Describe Postings of the treatment room regarding the Delivery Device: (review Postings requirements 10CFR20.1902)

2. Commit to personnel monitoring for all individuals in the treatment room

VI. Operating Procedures

A. Commit to following the device package insert instructions for use. Provide a copy of these instructions.

B. Commit to maintaining package receipt and source calibration records for inspection.

VII. Emergency Procedures

Commit to following the manufacturers device package insert instructions with respect to trouble shooting and preventing adverse events connected with administration.

VIII. Waste Disposal

Commit to surveying other waste generated during patient treatment. Commit to a minimum decay in storage time of ten-half lives and until indistinguishable from background for any materials found to be radioactively contaminated.

IX. QA Tests and Frequencies:

Commit to following the procedures as outlined in manufacturers package insert Quality Assurance/Quality Control (QA/QC) tests:

Commit to performing pre and post surveys of the source container and SIR-Sphere device.